UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

PREPROPOSAL CONFERENCE ON RFP NO. RS-OSD-79-010

A STUDY TO DETERMINE THE FEASIBILITY OF

CONDUCTING AN EPIDEMIOLOGIC INVESTIGATION
OF THE HEALTH EFFECTS OF LOW-LEVEL IONIZING RADIATION

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Room 113
White Building
7915 Eastern Avenue
Silver Spring, Maryland

Tuesday, 27 February 1979

The Panel convened, pursuant to notice, at 9:10 a.m.

PANEL MEMBERS PRESENT:

MR. [illegible] GUSTAVE
MR. RALPH E. LAPP
DR. MICHAEL A. PARENT
MR. ROBERT GOLDSMITH
DR. NIEL NELSON
MR. DAVID RUBINSTEIN
DR. SHLOMO S. YANIV

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P R O C E E D I N G S

MR. GUSTAVE: May I have your attention please. We're ready to start.

On behalf of the Nuclear Regulatory Commission, I'd like to welcome you here for the preproposal conference that's being conducted on RFP-RO903-79-010. This RFP is entitled "A Study to Determine the Feasibility of Conducting an Epidemiologic Investigation of the Health Effects of Low-level Ionizing Radiation."

My name is Raymond Gustave. I am responsible for this procurement. Also representing the NRC are, to my left, Ralph Avery; to my right, David Feldstein, Bob Goldsmith, Michael Farnoux; Dr. Shlomo Vaniv and from the EPA, Dr. Neil Nelson.

As you can see, the proceedings are being recorded. We're going to have a transcript made of the entire proceedings. A copy of this transcript is going to be sent out to everyone that received a copy of the origin request for proposal.

We'll also keep a copy on file in the division of contracts for anyone who wants to come in and take a lo at it.

This morning we hope to give you a little more insight into this procurement on low-level ionizing radiation.

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Right now I'd like to introduce Michael Parsont who is going to give you a little more insight. Oh, excuse one other thing before Mike comes on. Is there a Mr. John Strange here?

MR. [illegible]: Yes.

MR. GUSTAVE: We have a message for you to give Howard Bryant a call sometime this morning.

MR. PARSONT: Good morning, ladies and gentlemen. My name is Mike Parsont, and this morning I'll act as kind of a moderator to field questions, and I'd like to say that if there are some questions with which I have some difficul we will defer giving the final answers here until the panel meets and we get a consensus answer. Then we'll info you of that response as part of the amended RFP. I trust we'll be able to handle most questions completely at this t I might say that the panel was primed to respond to a great number of written questions. As it turns out, we were underwhelmed by a total of two, and -- both of which I will not respond to. Mr. Gustave will respond to them.

To give some background as to why we're here, we all know that there has been a great deal of controversy wi respect to the effects of exposure to low-level ionizing radiation. Both in the literature and in the Congressional hearings this has become quite evident. As a result of thi controversy, the NRC and EPA are mandated by Congress to pe

a feasibility planning study to determine whether follow on epidemiologic investigations are feasible on low-level ionizing radiation effects.

The RFP that you have received is the result of interagency discussions among EPA, NRC, HEW, the Veterans Administration, and DOD with comments by other people who were interested in seeing that work would be done.

The work scope was essentially designed by HEW, EPA, and NRC representatives, and our contracts people did their tailoring to fit the legalities. Following Mr. Gustave's response to the two written questions, I will take the floor again and ask for specific questions on your part, and we trust we can respond to those adequately.

MR. GUSTAVE: As Mr. Parsont said, we received an overwhelming response to the written questions, and the two that we have here were submitted by the Health Systems Division of Systemedics, Incorporated.

The first question reads as follows: "How rigid is the NRC's time schedule for phases I and II; providing there is no internal necessity for the 60 day limit on the tasks in phase I, it would seem more desirable to allocate four months to phase one and 11 months to phase II to ensure superior quality of work."

In answer to that question, it is imperative that the schedule be met. We have a mandate from Congress that w

have to meet, and we have to report to Congress by the end of September. So there is absolutely no leeway in the schedule.

The second question is: "Might task four of phase two be treated as an entity separate and distinct from the phase I work that must be completed within 60 days after the effective date of the contract? It requires substantial investigation of facts not often readily available in the literature."

The answer again to that question is, no, it's not possible. We must have this work completed so that we can report to Congress by the end of September of this year.

Now, we're going to be accepting questions from the floor. When you're acknowledged, please give your name and the company or organization that you represent.

As Mr. Parsont has said, if there are any questions that require any further research on our part, we'd like to have the opportunity to complete that research and provide you the answers in written form in the amendment that will be sent out on the RFP.

Now, I'd like to ask for questions from the floor and let Mike take over.

MR. PARSONT: I'd like to expand a bit about the times for the reports. NRC and EPA are required to respond to the Congress by April 1st on their needs and capabilities

in the area of low-level radiation research. That has [illegible], but this is just to bring you a little up to date on our problem with responding.

Initially the Congress desired the entire study to be completed by September 30th. It was rather obvious to the interagency group that met that in order to perform an adequate job that this could not be done by September 30th. Therefore, it was decided to construct a two phase study, the complete results of Phase I being the basis for the September 30th response to the Congress.

Therefore, one can see that it's imperative that the Phase I study be completed so that we can construct our report and put our report together for the Congress by September 30th.

Mr. Gustave stated that it is imperative that the final report be completed within the 15 month period of I endorse this: however, it must be recognized that if the successful bidder finds some supportive reason -- and it has to be a very good one -- that we will consider an extension. But for all intents and purposes, that 15 month time period we're looking at now has been fixed. I'd like to invite questions.

Don't let me down.

(Laughter.)

MR. GOLDSCHMIDT: I'm Peter Goldschmidt, Policy

1 [illegible] have a question on line 2, page 2. I wonder
2 if you could elaborate a little more on the purpose of
3 the 2 literature search?
4 MR. PARSONS: For those that don't have a copy of
5 the RFP, I'll read it for you. "Task one, Phase I: conduct
6 a literature search and identify various methods of
7 conducting epidemiologic investigations relative to the
8 effects of low-level ionizing radiation."
9 We believe that the successful bidder should
10 conduct a literature search and describe those epidemiology
11 methods which are applicable to the study of low-level
12 ionizing radiation effects. This should show some insight
13 on the part of the investigator into the types of problems
14 he might encounter in doing so.
15 Further questions?
16 MR. GOLDSCHMIDT: The types of problems in
17 actually carrying out the low-level ionizing radiation
18 research.
19 MR. PARSONS: It takes some insight.
20 MR. BLUM: Steve Blum, Mt. Sinai. In general,
21 it seems that you're encouraging the investigation of more
22 one population or the determination of feasibility of --
23 the feasibility of looking at more than one population. C
24 can approach that in the abstract, sort of an employed
25 population or a neighborhood population.

Now, let's say then that you have to get to the point where you have to know what kind of records these people have. Let's say even at Hanford. Would the people who are granted this contract have the power to go in and say to the health department in Denver or the people in the personnel department at Hanford, let me see exactly what kind of files you have, all of it, so I can determine whether there's enough to use the study.

MR. PARMENT: With respect to other governmental agencies, I know that NRC can provide liaison and make arrangements for investigators to see what data are there to look at or the studies that have been done. We've made arrangements at least with three agencies right now, and if the time arises or when the time comes, we can and we will provide entry to other governmental agencies.

I can envision where there might be some problems with private corporations and so forth, but we will do our best to assist the winning bidder in providing entry.

MR. BLUM: But can you bid on something if you're uncertain about getting entry? And in general are you encouraging -- it's sort of implicit, even explicit at point are you encouraging the investigation of more than one population in the feasibility study?

MR. PARMENT: Oh, yes.

MR. BLUM: Each one could be totally different?

the other.

MR. PARSONT: Yes. Well, we would expect that by the end of Phase I the populations should be well defined. If it appears during that phase that there might be some problems, then we can start working on that to help out because Phase II is where the actual data are going to be examined.

MR. PLUM: Then you're saying that Phase I ought to be a general statement of the benefits of examining certain kinds of populations to what one might expect, the kind of quality one might expect to find?

MR. PARSONT: Yes.

MR. GOLDSCHMIDT: I have a final question on the I want to understand whether military populations might be considered.

MR. PARSONT: I see no reason to consider them differently than any other populations, recognizing that on would have to be dealing with the military to get the data.

DR. DREYER: Nancy Dreyer, health systems divisi Could you comment -- are there any sort of criteria that NRC has set up for the selection of the bidders to whom thi would be awarded to? For example, are you interested specifically in any previous demonstrated experience in radiation?

MR. PARSONT: Oh, yes. If you read the selectio

criteria which are on page 20 or 19, the evaluation criteria on page 18, I think that's pretty self-explanatory. Also in, I believe, paragraph 18 a description of what we're looking for for technical content in the proposal.

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In the combination of these two lists covers pretty well the kind of areas we're looking for.

MR. KAPLAN: Jim Kaplan, ORI.

The bottom paragraph on page 19, where you talk about the potential conflict of interest between whoever gets the feasibility study and the follow-on study; how rigid is

I'm concerned about a number of people not wanting to bid on the feasibility study because of the follow on study. And it might work against your best interest, getting very good product out of the feasibility study and having to [illegible].

MR. PARSONS: We were quite concerned about this, and as it stands, you'll notice that if NRC is responsible for funding follow-on studies, studies resulting from this particular effort, then the winning bidder would be eliminated from participating in any follow-on study.

However, it is not clear, and I might say it's quite probable, highly probable that NRC will not be directly any follow-on studies.

It's more likely that DOE, or some other government agency, will have the responsibility. Only in the case where NRC is responsible for a follow-on study --

MR. BLUM: Are you including in this proposal reanalysis of secondary data that have already been collected

MR. PARSONS: We're not excluding that from consideration. What we do wish to discourage are studies th

require extrapolation from high doses to low.

DR. [illegible]: Which committee are you responding to?

MR. PARKINS: There are two: one on the House, one on the Senate side. One is the Hart subcommittee, and I can't recall in the House. (The Hall Committee).

The public law in which this study was stated was cited. I wonder if any of the panel members would have any comments.

(No response.)

MR. PARKINS: Shall we take a break for coffee? I'd also like to comment that the progress of this study will be watched very closely by the interagency group and we will be in close liaison and coordination with the National Institutes of Health and other HEW agencies.

I mentioned at the outset that a panel consisting of NRC, EPA, and HEW representatives constructed the basic work scope. This panel was established by a memorandum of understanding between NRC and EPA.

The panel consists of two members from HEW: Dr. [illegible] Mills, and Mr. George Simon -- pardon, that's EPA -- Dr. Charlotte Silverman of HEW, Mr. Frank Arsenault, Mr. Karl Goller of NRC, Dr. Gilbert Beebe from NIH is here. He has helped by commenting on the RFP and will be, maybe, a member and observer on the meeting of the interagency committee.

I also anticipate that there will be other

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representatives.

Further questions? Perhaps we should take a short time, ten minutes or so, to allow you to think some more about other questions and then try again.

(Brief recess.)

MR. PARSONS: Ladies and gentlemen, have your fertile minds developed any further questions?

Mr. Blum?

MR. BLUM: I'm still not certain I understand all of this. Phase I is really, again, a general statement of the problem area and the approach one would use in resolving this issue.

Phase II involves already field examinations and really getting your hands dirty.

So it seems to me since we're uncertain as to the accessability of data in Phase II, especially if it's not a government installation, it seems to me that we really can't make very specific statements about what we will do in Phase when we would respond to this request from the proposal.

In other words, what I'm saying is it seems that the proposal itself is essentially limited to the elements in Phase I. And even in Phase I, let's say Task 4 is already field studies. You have to go out and see the size of the population, the variability in local background radiation, the mobility rates. All that is already beyond

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description. It is data collection and it's due in 60 days.

MR. HAWKINS: When one looks at the matrix and looks at it in very, very great detail, I would agree with that.

Certainly, there are data available about background levels, the mobility of certain types of populations and so forth which can be considered without going out to the field.

It's also quite possible that some of the populations which may be the result, or chosen as being feasible to carry on Phase II at some later time may indicate some great difficulties in getting the actual data.

This is something that we recognize.

But the Phase I task is set to delineate those populations which will be studied more closely in Phase II, recognizing that it, in fact, might not be possible to find some of the data.

Also, you'll note that in Phase I that a certain amount of understanding must be present on risk estimators and so forth.

These can be gotten from whatever publications are available. They do not limit the investigator to any specific publications. We make some recommendation, but if the investigator has other references that he cares to use, that's acceptable.

We do not expect that this will be a simple task.

MR. GOLDSCHMIDT: I have a series of questions if you'd like to have them all at once.

In terms of Phase II, it appears that from what I heard earlier today, you expect people to go out and do some [illegible]. Is that correct?

MR. PARSONS: Yes.

MR. GOLDSCHMIDT: In view of that, would you give a general travel estimate as a planning figure. Since we don't know where we're going, that cost estimate would vary greatly, depending on where these records might be.

MR. PARSONS: In our estimate of the time necessary to perform the study, two man-years was a guess, if you will, for assessing the data, field data.

MR. GOLDSCHMIDT: That would include the travel costs?

MR. PARSONS: Not necessarily. That would be up to the bidder to give an estimate.

MR. GOLDSCHMIDT: Now the Task 4 in Phase II. Are you talking about [illegible] with respect to medical surveillance procedures? For example, as under the OSHA act requiring low dose radiation?

MR. PARSONS: We're leaving this open to the investigator to recommend whatever he feels is appropriate and necessary.

MR. GOLDSCHMIDT: And Task 5, I'm not quite clear as to the purpose of Task 5, given that you appear to have isolated control populations from study populations.

In other words, what would be accomplished, in your view, by Task 5?

MR. PARSONI: We realize that there are certain populations for which there may not be appropriate field data, and we would like the bidder to estimate what it would take to make those, or to construct the data or reconstruct the data, or in some manner provide the data for those groups.

MR. GOLDSCHMIDT: Are these control populations related to study populations previously identified?

MR. PARSONI: They may be.

For example, for a study population which is fairly well defined and which may present difficulties on the control side, and in that particular situation, if one feels that this is an excellent study population, but for the lack of adequate control population, that it becomes less feasible to carry out the study -- then we'd like to see some sort of written instruction, or some sort of an approach to build or to tailor the control population.

MR. GOLDSCHMIDT: That's the intent of Task 5.

MR. PARSONI: Yes.

MR. GOLDSCHMIDT: One last question. It relates to

Task 2 a) ii. I'm not clear of the meaning of that.

It says, "Describe the [illegible] bound of risk of ra-
tion-induced cancer."

MR. RUBINSTEIN: Any plausible numerical upper
boundary, [illegible] confidence limit or other considerations,
be chosen.

MR. PARSONT: What I propose to do is that we'll
diagram that, define it quite closely, and compound.

MR. GOLDSCHMIDT: Thank you.

MR. RUBINSTEIN: This is more of a wish than a
carefully-thought-out process that we have in mind here. A
to the extent that the bidder displays ingenuity, it will
in his favor toward getting the contract.

MR. PARSONT: We'll define it closely.

MR. GOLDSCHMIDT: Are you talking about sensitiv
analysis as to the risk involved, or are you asking for rec
mendation of exposure levels?

MR. PARSONT: Let's withhold that.

Is there another question here?

DR. HOOTON: Hooton, University of Pennsylvania.

On the conflict of interest question, how deep w
that necessarily go? Does it apply only to the prime con-
tractor? Does it apply to the subcontractor? Does it appl
to consultants who may have been consulted by the prime con
tractor?

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MR. PARSONS: Mr. Avery?

MR. AVERY: I think that it should apply to lower tier people, as well as the price. The exclusion stated here is pretty much absolute. But during the negotiation process you can explore it further if you have questions or questions. But I think it should apply to lower tier people, too, as well as to the price.

As far as their possibility of getting a follow-on effort from the NRC --

MR. CLARK: Clark from Enviro-Control.

I'd like you to comment on Task 3 of Phase II regarding other deleterious health effects. What sort of effort and how much emphasis do you have in mind for that portion of the study?

MR. PARSONS: We feel that some consideration should be made of other deleterious health effects such as potential genetic effects, considerations of, if one will, unspecific life span shortening.

There are a whole list of potential health effects. We do expect, however, that the main emphasis should be on those health effects which are recognized as being major potential health effects from exposure to low level ionizing radiation.

DR. STRANGE: Strange, Franklin Institute.

I think you raised a question when you answered t

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significant potential health effects. Are we now limiting this to effects in adults?

You're not excluding unborn?

MR. PARSONT: No, we're not excluding unborn.

DR. STRAUSS: I was trying to figure out if you were talking about -- if Task 3 was where we were being concerned with these ideas, or whether or not what you just said implied that the main emphasis was to be conducted on populations.

MR. PARSONT: I think Task 3 is presented so that we can get a full view rather than concentrating in one specific area.

We recognize that the controversy is not specific over carcinogenesis, but over other effects as well.

MR. PARSONT: If there are no other questions --

DR. HOOTON: I have just one small point.

Would it be possible to have the transcripts and any revisions sent to people who are here even if they're not on the original list of RFP recipients?

MR. GUSTAVE: Oh, yes. You will have to register, though.

DR. HOOTON: I did register, but I didn't get the RFP originally.

MR. GUSTAVE: Then we don't have your address, so you're going to have to register with your complete mailing

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1 sources so we can send you a copy.
2 MR. STARKS: Can you give us an estimate as to
3 when these transcripts will be available?
4 MR. GUSTAVE: I hope to get them in the mail by the
5 end of this week. The biggest problem is going to be getting
6 them duplicated.
7 So depending on how long it takes to get that
8 accomplished will determine exactly when they're in the
9 mail.
10 Hopefully, at the latest by Friday, so that they
11 can be delivered Monday.
12 MR. PARSONS: I'd like to thank you, ladies and
13 gentlemen.
14 (Whereupon, at 10:00 a.m., the hearing adjourned.
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B. OTHER CONSIDERATIONS

1. Cost Evaluation

A separate cost analysis will be performed on each business proposal. To provide a common base for evaluation of business proposals, level of effort data shall be expressed as man-hours.

Award will be made to the offeror presenting the best overall proposal with consideration being given to Organizational Capabilities, Technical Approach, and Estimated Costs. The relative importance of Organizational Capabilities and Technical Approach is shown by the numerical weights assigned to each. Estimated Costs is less important than the other two areas. Award will not necessarily be made to the offeror with the lowest estimated costs. Estimated Costs will be determinative only when there is no substantial difference in the aggregate quality of the Organizational Capabilities and Technical Approach between offerors being considered for award.

The government reserves the right to make an award to the best advantage of the government, cost and other factors considered.

2. Conflict of Interest

There are two paramount principles which the Commission must consider in determining if a conflict of interest would exist by award of this work.

(a) Might the award in any way give rise to a conflict that biases or prejudices the results that the Commission expects?

(b) Might the award put the contractor in an unfair competitive advantage with respect to other contractors?

In order to assist the Commission in applying the above two principles to submitted proposals, the offeror should describe any significant contractual and organizational relationships of the offeror, its employees or expected subcontractors on this contract, with industry associations (e.g., utilities, etc.) and suppliers thereof (e.g., architect engineers and reactor manufacturers, etc.) which might give rise to an apparent or actual conflict of interest in the event of a contract award to an offeror. Examples of some of the relationships which would be of concern to the NRC in this context are generally described in the NRC General Statement of Policy Regarding the Avoidance of Contractor Organizational Conflicts of Interest, copy of which is attached for your information.

The possibility that an offeror which receives this contract could benefit from the conclusion that further epidemiologic research is feasible by way of participating in such a follow-on effort gives rise to an inherent conflict of interest. It is therefore anticipated that the contract will contain language excluding the successful offeror from participating in follow-on effort in the event that such follow-on effort is undertaken by the NRC.

FOR THE PART ...

SECTION E

PART III

CONTRACT SCHEDULE

SCOPE OF WORK, TERMS AND CONDITIONS

ARTICLE I - STATEMENT OF WORK

A. HISTORY

The Energy Reorganization Act of 1974, as amended, abolished the Atomic Energy Commission (AEC) and created a new agency, the Nuclear Regulatory Commission (NRC), to which was transferred the licensing and related regulatory authority of the AEC under the Atomic Energy Act of 1954, as amended. The Energy Reorganization Act also added authority for the NRC to license and regulate certain facilities of the Energy Research and Development Administration (ERDA), which was also created by that Act.

PROJECT TITLE: A Study to Determine the Feasibility of Conducting an Epidemiologic Investigation of the Health Effects of Low-Level Ionizing Radiation

B. BACKGROUND AND OBJECTIVES

To improve the scientific basis for their regulatory activities, the Nuclear Regulatory Commission and the Environmental Protection Agency in consultation with the Department of Health, Education and Welfare, will support a study to assess the feasibility of performing epidemiologic investigations of the health effects induced by exposure to low-levels of ionizing radiation. The purpose of this feasibility study is to ascertain the overall value and likelihood of scientific merit of such epidemiologic investigations.

The dose levels of primary interest are those applicable to exposures experienced by populations both in the work place and the general environment. Single, repeated and continued exposures should be considered.

It can be assumed that the human health effects induced at low-levels of radiation exposure are similar to those observed normally in human populations. Based on the present body of knowledge, the predominant detectable health effect is the induction of neoplastic diseases. However, there are other human health effects for which quantitative risk estimates are available. Such effects are also of interest in this study. Publications of the Committee on the Biological Effects of Ionizing Radiation (BEIR) of the National Academy of Sciences, of the United Nation's Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and other relevant publications should be used as references for these effects. These references should also be consulted in making assumptions on dose-effect relationships and corresponding risk estimates.

The overall objectives of this feasibility study are:

(i) to define the statistical, technical, and administrative strengths and constraints which are inherent in the conduct of epidemiologic studies on subjects exposed to low-level ionizing radiation.

(ii) to examine the merit of conducting such epidemiologic studies on the health effects of low-level ionizing radiation exposure in light of the strengths and constraints identified in (i) above, current knowledge of biological effects and the characteristics of candidate populations.

C. STATEMENT OF WORK

The Contractor shall provide the necessary personnel, facilities, materials, and services to accomplish the specific tasks listed below. The effort hereunder will be accomplished in two phases, the details of which are presented in the scope of work which follows.

Phase I. PRELIMINARY ANALYSIS OF STATISTICAL STRENGTHS AND LIMITATIONS

Task 1) Conduct a literature search and identify various methods of conducting epidemiologic investigations relevant to the effects of low-level ionizing radiation.

Task 2) Provide a specific evaluation of the strengths and limitations of epidemiologic methods to estimate the risk of health effects from exposure to low-level ionizing radiation in various populations receiving radiation doses in excess of "normal" background levels. The contractor may propose and evaluate any suitable epidemiologic methods not identified by the literature search.

The evaluation shall address the influence of data quality, potential confounding or effect-modifying environmental, demographic and other pertinent factors; the possible acquisition of adequate population size for study; and the capacity to discriminate between incremental radiation induced risk and existing "normal" risk of health effects.

Task 3) Based on currently available risk estimates and dose-effect relationships, assess the likelihood of epidemiologic studies distinguishing incremental radiation induced health effects from conditions and disorders normally occurring. The most recent reports of the BEIR Committee, UNSCEAR and other relevant publications shall be used as guides for both of these factors. The range of risk estimates shall be included in the analyses, based on whichever publications are selected.

The populations identified for this purpose shall include, but do not have to be limited to: occupationally exposed individuals; residents in areas with high natural and/or technologically enhanced background; residents in areas of nuclear facilities;

and groups exposed during medical procedures other than for the treatment of neoplastic diseases. Populations which have been the subject of previous epidemiologic investigations of the effects of low-level ionizing radiation shall also be included.

Task 4) Determine which of the populations identified in Task 3 above are most suitable for epidemiologic studies of the health effects of low-level ionizing radiation. Determination shall be based on such factors as study and control population composition and size; potential confounding factors; variability in local background radiation; variability in local rates of health effects; and population mobility. Explain why other populations identified in Task 3 above are not considered suitable for further study, and examine at what level of risk and/or exposure epidemiologic studies on such populations become feasible.

Note: Phase I must be completed and a report submitted to the NRC within sixty (60) days after the effective date of the contract.

Phase II. DETAILED SCIENTIFIC CONSIDERATIONS OF FEASIBILITY AND COST BASED ON FIELD EXAMINATION OF RELEVANT POPULATION CHARACTERISTICS.

Task 1) For each of the populations identified in Phase I, Task 4, as suitable for epidemiologic studies on health effects of low-level ionizing radiation, determine the nature, form, extent, quality and accessibility of existing health and radiation exposure data. Radiation exposure data should take into account the various characteristics of the different types of ionizing radiations. The Contractor shall identify and estimate the magnitude of the uncertainties in the radiation exposure data.

Investigate and discuss potential control populations and evaluate their potential contributions to an epidemiologic study or studies and provide cost estimates for such studies. Identify and assess potential confounding and effect-modifying factors relative to the study and control populations under consideration. Recommend those specific sources of data most appropriate to such a study.

Task 2)a Assess, based on Task 1, if it is possible to accomplish with existing data (for specific cancer sites, types and total cancer) either or both of the following objectives:

(i) Describe and quantify, using models and statistical analyses, including confidence intervals, the excess of cancer arising from exposure to low-level ionizing radiation. Include a discussion of considerations of study and control population size with different anticipated levels of risk and exposures and how confidence limits are affected by variations in these parameters.

(ii) Describe an upper bound of risk for radiation-induced cancer

It is not intended that the contractor will develop specific models. However, the contractor can select appropriate models for illustrative purposes.

2)b For each population and epidemiologic approach considered, analyze the interrelationships among scope, duration and and cost.

Task 3) Explore which, if any, other deleterious health effects resulting from exposure to low-level ionizing radiation can be successfully studied in epidemiologic investigations of the selected populations.

Task 4) Identify how current data bases and record keeping practices could be improved for continuing epidemiologic studies in this area. This shall include identification of possible new data bases and record keeping practices that should be initiated to support epidemiologic studies in the future.

Task 5) For potential control populations that were eliminated from further consideration because of the lack of readily available health or exposure data, identify those, if any, for which some useful estimate could be obtained by field reconstructuion of the necessary data. For such populations, estimate the effort that would be involved in collecting (or reconstructing) the necessary data and the quality of the expected epidemiologic results.

D. REPORT REQUIREMENTS

The technical reports listed below are to be documented, produced and disseminated in accordance with NRC Manual Chapter 3202, which is part of this contract.

1. SPECIFIC REPORT REQUIREMENTS

a. Monthly letter progress report, in one (1) copy to the Contracting Officer's Authorized Representative (COAR) and one (1) copy to the Contracting Officer, shall be due by the 10th day of each month and shall include as a minimum:

i. A technical report of progress describing findings to date, problems incurred and solutions proposed, and plans for the ensuing month.

ii. A report of costs incurred to date as follows:

Direct Labor Costs
Travel Expenses
Overhead
Additional Costs
Forecasts for Contract Completion

b. Within sixty (60) days after the effective date of the contract, the contractor shall submit a comprehensive report on the final results of Phase I.

c. A comprehensive summary report on the results of Phase I and results to date obtained on Phase II shall be submitted on August 31, 1979.

d. A progress report on Phase II shall be submitted two (2) weeks prior to the eighth (8th) month meeting.

e. The final report shall be submitted in one (1) reproducible (camera-ready) copy and five (5) copies to the COAR and one (1) copy to the Contracting Officer.

E. SCHEDULE

Phase I - Complete within sixty (60) days after award of contract

Final Report - Complete within fifteen (15) months after award of contract

F. MEETINGS

The contractor shall participate in various meetings with the NRC staff during the contract period. The schedule of these meetings follows:

(1) Approximately two weeks after the effective date of the contract, members of the NRC staff shall meet with the contractor's representatives at the contractor's facility (place of performance) to discuss the progress and direction of Phase I.

(2) On September 10, 1979 (at a time to be assigned at a later date), the contractor shall meet with members of the NRC staff at the NRC offices, Nicholson Lane, Rockville, Maryland, and be prepared to discuss the August 31, 1979 report.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
CENTER FOR DISEASE CONTROL

NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
ROBERT A. TAFT LABORATORIES
4676 COLUMBIA PARKWAY, CINCINNATI, OHIO 45226

June 27, 1979

Dr. Elliott Stonehill
Program Analysis and Formulation Branch
National Cancer Institute, NIH
Building 31, Room 10 A 52
Bethesda, Maryland 20205

Dear Dr. Stonehill:

At the request of Dr. Anthony Robbins I am sending you the material I received June 25, 1979 from NRC staff members, Mr. Robert Purple and Mr. Mike Parsont. After a review by and reaction from NIOSH staff it is our plan to meet with Mr. Purple and his staff for the purpose of discussing the data needed for establishing a registry of TMI workers.

Sincerely yours,

Todd M. Frazier

Todd M. Frazier
Chief, Surveillance Branch
Division of Surveillance, Hazard
Evaluations, and Field Studies

Enclosure

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